

## **REMARKS/ARGUMENTS**

Claims 1-12 have been rejected under 35 U.S.C. § 103(a) on the basis of obviousness. Applicant resubmits claims 1-12 as amended, together with new claims 13 and 14 and arguments for their allowability.

### **The Claim Amendments**

Independent claims 1 and 8 have been amended to more precisely set forth those novel features of Applicant's invention that distinguish it over the cited prior art and make it non-obvious. In this regard, both claims 1 and 8 have been amended to specify that the gasket that is disposed in the vent recess is wholly within the vent recess where it is protected against damage. These limitations do not add any new matter, as they are clearly shown in Figs. 4 and 5 originally submitted with the application. The other amendatory matter in claims 1 and 8 have been added for the purposes of clarification and support for the additional limitation set forth above and do not introduce any new matter. Claims 5 and 10 have been amended to specify that the spaces between the vent and the filter cover are at the location of the vent. Once again, that is well supported in the original application and shown in Fig. 5.

Claim 9 has been amended to eliminate any 112 problems as pointed out by the Examiner. The Examiner's expressed working interpretation of the meaning of the claim is in accord with Applicant's.

### **New Claims**

New claims 13 and 14 include the limitation that the gasket in the recess has a concave cross-section. This limitation, together with the limitation

added to claims 1 and 8 that the gasket is wholly within the recess, further distances the claimed invention from the prior art.

### Obviousness

The issue of obviousness and how it can be established was the subject of the recent Supreme Court decision in *KSR International Co. v. Teleflex, Inc.*, in which the Court reviewed the Federal Circuit's use of the "teaching, suggestion or motivation test" (TSM test) with the Court ultimately finding that the application of that test as to the facts in the *KSR* case was too restrictive and led to the incorrect result. The Supreme Court referred to *Graham v. John Deere* as still providing the factors to be looked at in testing for obviousness, but it also confirmed the usefulness of the TSM when properly applied:

"In the years since the Court of Customs and Patent Appeals set forth the essence of the TSM test, the Court of Appeals no doubt has applied the test in accord with these [*Graham*] principles in many cases. There is no necessary inconsistency between the idea underlying the TSM test and the *Graham* analysis."

In its opinion, the Supreme Court made the following statements that guide the obviousness analyses:

- "Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness."
- "As is clear from cases such as *Adams*, a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art."
- "It can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions

- in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.”
- “A factfinder should be aware, of course, of the distortions caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning. See *Graham*, 383 U. S., at 36 (warning against a ‘temptation to read into the prior art the teachings of the invention in issue’ and instructing courts to ‘guard against slipping into the use of hindsight’ (quoting *Monroe Auto Equipment Co. v. Heckethorn Mfg. & Supply Co.*, 332 F. 2d 406, 412 (CA6 1964))).”

The following *Graham v. John Deere* factual inquiries for obviousness were set forth in the Office Action:

1. Determining the scope and content of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence presented in the application indicating obviousness or nonobviousness.

It does not appear that the Examiner has applied the TSM test, at least there does not appear to be anything in the Office Action indicating so, or a reference to any prior art that would meet that test.

#### Application Of The *Graham* Factors To The Amended Claims

The Examiner relies on Wagner '390 and Wagner '390 combined with Frieze (WO99/40948) in arriving at the conclusion of 103(a) obviousness as to all claims.

#### Scope And Content Of The Prior Art

Using the cited references to determine the scope and content of the prior art, it can be said that a vent seal in a sterilizing container utilizes a gasket

having a circular cross-section disposed in a recess wherein a substantial portion of the gasket extends outside of the recess (see Fig. 10 of Wagner '390 and Fig. 1A of Frieze). In forming a vent seal in these references, the gasket must extend outside of the recess to engage the closing flat surface. That is to say, if the gasket were wholly within the recess, it would not form a seal with the flat portion of the closing surface.

Thus, the scope and content of the prior art regarding seals for a sterilization container vent includes gaskets in a gasket recess wherein the gasket extend substantially beyond the recess for engagement with a flat surface to form a seal.

#### Differences Between The Prior Art And The Claims At Issue

Claims 1 and 8, as now amended, require that the gasket be disposed wholly within the vent recess for its protection, which is a substantial difference from the cited prior art. A further difference between the prior art and the claimed invention, as set forth in claims 1 and 8, is that the cover surface is not flat (planar), but rather has a ridge in a planar surface that is coextensive with the gasket vent recess and sized to fit within the vent recess and apply pressure against the gasket disposed wholly within the vent recess.

#### Resolving The Level Of Ordinary Skill In The Pertinent Art

Applicant does not see where in the Office Action this *Graham* factor has been addressed.

#### Obviousness As To Claims 1- 6 And 8-11 Based On Wagner Alone

After pointing out the basic elements of a prior art vent seal in Wagner

(‘390) (an O-ring in a recess that surrounds the vent), it is acknowledged that Wagner does not teach one of the claim limitations, *to wit*, a filter cover having a ridge that fits into the recess.

In support of the Examiner’s conclusion that the difference between the prior art and Applicant’s claimed invention would have been obvious, the Examiner points to the portion of Wagner that discloses: the “filter holder plate is fixed on the outer edge of the intermediate cover in any desired way, for example by clamping . . . [so that] no cavities remain upon deliberate dismantling (e.g. filter replacement or filter inspection).”

It is then argued that:

“clamping” is deemed to incorporate the configuration of clamping the filter cover/holder plate through a ridge appropriately sized which can be forced into the vent recess to produce a clamping effect, as this configuration is a well known closing mechanism (which is exemplified in Figures 1,6 and 9-11 to effect closing of the sterilization container through the recess in cover 12 on 10 via a sealing ring 14), in order to provide a closing mechanism between the lid/cover (12A) and filter cover/holder plate (62).

Applicant submits that the proposed modification of Wagner would not be operative unless reconstructed in a manner suggested only by Applicant.

Applicant understands the suggested modification of Wagner as follows:

(1) Wagner’s outer edge securing mechanism is eliminated; (2) the flat cover plate is modified to have a knife-edge rim that is coextensive with and sized to fit into the recess in the vent; (3) the size and shape of the O-ring that Wagner illustrates is modified so that it allows the rim in the cover plate to enter the recess and not be forced out by the elasticity of the O-ring; and (4) the rim and the recess have an interference fit that clamps the entire cover plate in place

on the intermediate cover sufficiently to maintain integrity of the seal.

In every prior art sealing arrangement between a vent and vent cover known to Applicant, the means for securing the cover over the vent is separate from the seal means and for good reason. The seal is formed by forcing a rigid part against an elastic part. The elastic part (typically an O-ring) is deformed and pushes back against the ridged part (typically a flat plate). It is the separate clamping mechanism (39 in pending application; 12A in Wagner) that supplies the force necessary to maintain engagement between the elastic gasket member and the cover plate. The proposition by the Examiner that these two functions be combined is contrary to good practice and not a combination that would be made by one skilled in the art since it would not result in either an effective seal or a well secured cover plate.

It is asserted that such an arrangement (seal and clamp combined) is a well known closing mechanism based on Wagner's illustration of the connection between the intermediate cover 12 and the container 10. Rather than connecting and sealing two relatively flat members (vent and vent cover), the container 10 presents an upstanding knife-edge rim. The invention disclosure of Wagner is not directed to a connection between a sterilization container and its cover or even a seal between a vent and a vent cover plate. Those features are simply mentioned in passing as part of the overall container, not the invention. Wagner's invention is directed to valves for equalizing pressure differentials. Applicant seriously doubts that Wagner would not have a separate securing mechanism for the intermediate cover 12.

In any event, the intermediate cover has the application of gravity applying a force keeping it on the upstanding rim of container 10.

More importantly, the argument in support of obviousness is the kind of hindsight reconstruction long criticized and disallowed by the USPTO Board (see *Ex parte Beuther*, USPTO Bd 71 USPQ2d 1313, 2004: "In short, the only suggestion for this proposed combination stems from hindsight knowledge impermissibly derived from the appellant's disclosure." at 1317; the Federal Circuit (see *In re Fine*, 5 USPQ2d 1596 (CAFC 1988) and the Supreme Court. As pointed out above, in *KSR*, the Supreme Court reminded that such reconstruction based on an applicant's disclosure is not permitted to establish obviousness:

"See Graham, 383 U. S., at 36 (warning against a "temptation to read into the prior art the teachings of the invention in issue" and instructing courts to "guard against slipping into the use of hindsight" (quoting *Monroe Auto Equipment Co. v. Heckethorn Mfg. & Supply Co.*, 332 F. 2d 406, 412 (CA6 1964)))."

Furthermore, no reason is identified that would have prompted one skilled in the art to make the suggested modifications to Wagner. The importance of such reasons is made manifest in *KSR* where the Court states:

It can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.

The unassailable fact that one skilled in the art would not have had a reason to use the arrangement for connecting the intermediate cover to the container in place of the connection between the vent and its cover is revealed

by the fact that Wagner did not. And he did not because it would not have worked for the reasons given above.

Thus, claims 1 and 8 as amended clearly define Applicant's invention over Wagner in a non-obvious way.

Claims 2-7 and 9-14 are allowable, along with independent claims 1 and 8 from which they depend.

Claim 10 has been amended to specify that filter cover and the container wall containing the vent are spaced apart at the location of the vent. This is not the case in Wagner. The space allows the holes in the wall to be off-set from the holes in the cover (which is not the case in Wagner) to allow and promote mixing of the sterilization media.

#### Obviousness As To Claims 1- 6 and 8-11 Based On Wagner And Frieze ('948)

Once again, it is acknowledged in the Office Action that neither Wagner nor Frieze teaches the limitation of a filter cover with a ridge sized to fit into the vent recess. Both teach only a gasket having a circular cross-section. To overcome this deficiency, once again, the same argument is put forward for modifying Wagner by substituting Applicant's ridge and recess (wholly containing the gasket) combination for Wagner's recess and flat cover combination (in which the gasket extends outside the recess). The same reasons given above for why that is not a non-obvious combination apply here and, although fully asserted, are not repeated.

#### Conclusion

It is through a novel arrangement of parts that Applicant's claimed

sealing arrangement is able to protect the filter seal gasket from damage and thereby maintain an effective seal even after numerous filter changes and sterilizer cleanings. The prior art arrangements as exemplified by Wagner and Frieze expose the gasket when the filter cover is removed which frequently results in gasket damage and a compromised seal. For all of the reasons given above, Applicant submits that the amended and new claims are allowable.

Respectfully Submitted,

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